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April 22, 1997 (Date of Deposit)

4-22-97 J. Kausz
Date Name

130-58-6

File No.: 5407/0B426

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JIM L. NELSEN, ET AL.

Serial No.: 08/759,765 Group Art Unit:

Filed: December 3, 1996 Examiner:

For: CARNITINE SUPPLEMENTED DIETS
FOR GESTATING AND LACTATING SWINE

**TRANSMITTAL OF PROCESSING AND RETENTION FEE
UNDER 37 C.F.R. § 1.21(l)**

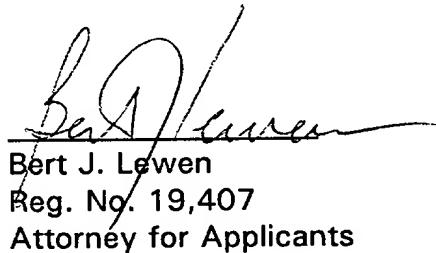
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Washington, DC 20231

Sir:

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A Notice to File Missing Parts of Application - Filing Date Granted, a copy of which is enclosed, was mailed on February 7, 1997. The processing and retention fee is submitted within one year of the notification that the filing fee is due.

Respectfully submitted,



Bert J. Lewen
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805 Third Avenue
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File No: 5407/0B426

Date: December 3, 1996

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Washington, DC 20231

Sir:

Enclosed please find an application for United States patent as identified below:

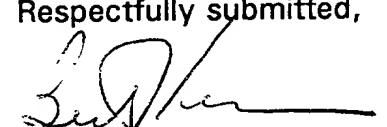
Inventor/s (name ALL inventors): Jim L. NELSEN, Robert D. GOODBAND, Michael D. TOKACH, Kevin Q. OWEN, Stephen A. BLUM, and Rene BLUM

Title: CARNITINE SUPPLEMENTED DIETS FOR GESTATING AND LACTATING SWINE

including the items indicated:

1. Specification and 16 claims: 3 indep.; 13 dep.; 0 multiple dep.

Respectfully submitted,


Bert J. Lewen
/ Reg. No. 19,407
Attorney for Applicant(s)

(D&D Forms/PTO-1)

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**CARNITINE SUPPLEMENTED DIETS FOR GESTATING
AND LACTATING SWINE**

FIELD OF THE INVENTION

The present invention is in the general field of
15 swine farming and relates to the feeding of swine during the
gestation and lactation period to increase the pork
productivity by increasing the number of pigs per litter, and
litter and pig weaning weights. Swine diets of this invention
include carnitine, such as L-carnitine or L-carnitine salts,
20 present in the amount effective to increase the number of pigs
per litter and litter and pig weaning weights.

BACKGROUND OF THE INVENTION

Carnitine is a naturally occurring B vitamin-like
25 compound found in humans and other mammals. Carnitine has many
functions, but its primarily role is in the transport of fatty
acids into the mitochondria. Previous research (U.S. Patent
Nos. 5,124,357 and 5,192,804) has shown that carnitine
supplementation of diets increases the lean to fat ratio of
30 pigs. Its beneficial effects of increasing carcass leanness
and improving the lean to fat ratio were also shown in fish
(U.S. Pat. No: 5,030,657). In addition, carnitine has been
shown to improve the hatchability of eggs when fed to laying
hens (U.S. Patent No. 5,362,753).

35 Carnitine is synthesized in the body from two essen-
tial amino acids, protein bound lysine and methionine. The
level of enzyme involved in the synthesis of carnitine is
extremely low in newborn piglets (Coffey et al., *Carnitine
Status and Lipid Utilization in Neonatal Piglets Fed Diets Low
40 in Carnitine*, J. Nutr. 121:1047-53; 1991). The newborn piglet

must quickly switch from carbohydrate transplacental nourishment to a high-fat milk based diet. Thus, during the suckling period, the neonate must quickly develop the capacity to oxidize fatty acids and ketone bodies as fuel alternatives to carbohydrates. Given the role of carnitine in the fatty acid metabolism, its availability to newborns in adequate amounts is essential (Borum, P.R., *Variation in Tissue Carnitine Concentration with Age and Sex in the Rat*, Biochem J. 176:677; 1978).

The primary source of carnitine in neonatal tissue, at least 2-3 days *post partum*, is milk (Robles-Valdez et al., *Maternal Fetal Carnitine Relationships and Neonatal Ketosis in the Rat*, J. Biol. Chem. 251:6007; 1976). The presence of carnitine in the milk should enhance the piglets' ability to utilize milk fat. Coffey et al. compared lipid utilization by pigs nursing from their sow with lipid utilization by pigs fed a milk replacer with or without added carnitine and found that nursing pigs were heavier than pigs fed milk replacer. However, pigs fed the milk replacer with added carnitine grew faster (day 7 to 21) than those fed the milk replacer without carnitine. Carnitine supplementation did not affect lipid or glucose status of the pig.

Other researchers have described the effect of supplemented carnitine on milk production and fatty acid metabolism. Erfle et al. (*Effect of Infusion of Carnitine and Glucose on Blood Glucose, Ketones, and Free fatty Acids of Ketotic Cows*, J. Dairy Sci. 54:673-80; 1971) infused carnitine into ketotic lactating dairy cows and found improved fatty acid oxidation.

As noted above, the availability of carnitine in the diet of newborn pigs is essential for efficient transition to a high-fat milk diet. However, methods for supplementing the milk diet of nursing pigs with carnitine are presently unavailable. Use of milk replacer containing carnitine as

suggested for cows would not be practicable on a large commercial scale. More importantly, milk replacers do not contain all other essential components of the swine milk. It has now been surprisingly discovered that feeding gestating and 5 lactating swine with a diet supplemented with carnitine has a positive effect on nursing pigs. It has now been shown that litter and pig weaning weights, as well as the number of pigs per litter, increase when swine is fed the diet of the invention comprising carnitine.

10

SUMMARY OF THE INVENTION

The present inventors have surprisingly discovered that feeding carnitine to gestating and lactating swine increases litter and pig weaning weights as well as the average 15 number of pigs per litter thus increasing pork productivity. These beneficial effects are likely to be a result of carnitine effect on swine milk production and/or the level of carnitine in the swine milk.

Accordingly, one aspect of the present invention is a 20 feed formulation for gestating and lactating swine comprising carnitine in the amount effective to improve litter and pig weaning weights.

Another aspect of the present invention is a method of increasing litter and pig weaning weights by feeding gestating and lactating swine a diet supplemented with carnitine. 25

A further aspect of the invention is a method of increasing the number of pigs born per litter by feeding gestating and lactating swine a diet supplemented with carnitine.

30

DETAILED DESCRIPTION OF THE INVENTION

All patents and literature references cited in this specification are hereby incorporated by reference in their entirety.

The present invention relates to a diet for gestating and lactating swine which comprises carnitine, and a method for increasing litter and pig weaning weights and/or the number of pigs per litter.

5 In the practice of this invention, female swine are fed a diet of the invention during their respective gestation and lactation periods or for a portion of said gestation or lactation periods. The gestation diet is fed from approximately mating until parturition and the lactation diet is fed from 10 parturition until offspring are weaned or lactation is terminated by decision of the herdsperson.

To increase the pig and litter weaning weights, the diet is fed during gestation and lactation or during lactation only. To increase the number of pigs born alive, the diet is 15 fed during gestation.

The feed formulation of the invention comprises carnitine. The supplemental carnitine can be any isomer of carnitine, preferably L-carnitine. Also suitable for formulation of the diet of the present invention are salts of 20 carnitine, such as acetyl carnitine, and di-carnitine-tartrate. These materials may be encapsulated or protected.

The carnitine is present in the feed formulation of the invention in an amount effective to achieve the desired improvement of litter and pig weaning weights, as well as of 25 the number of pigs per litter. This improvement can be of any level above the litter and pig weaning weights obtained from gestating and lactating swine fed the diet without the carnitine, as even the small differences in weaning weights have significant effect on meat productivity. For example, the 30 diets of the present invention decrease fixed investment costs and production costs since the period from the pig birth to the meat market is shorter than when swine are fed conventional diets.

Generally, the feed formulation of the invention contains from about 5 to 5,000 ppm of carnitine, preferably 5 to 200 ppm. Given the detailed guidance of the present specification, it is believed that it is within the level of one of 5 ordinary skill to test a range of carnitine concentrations using a trial feed in order to optimize the concentration for the particular breed and stage of development being fed.

The base diet of the present invention can be any typical swine diet known in the art, including those formulated 10 for gestating and lactating swine. Generally, a typical diet will include a selection of the ingredients described below. Extensive guidance in formulating diets for the feeding of swine can be found in "Nutrient Requirements of Swine", Nutrient Requirements of Domestic Animals, Number 3, 9th rev. ed. 15 (National Academy of Science, Washington, D.C. (1988)).

In the United States, most swine are fed a diet consisting of about 97% corn and soybean with the remaining 3% consisting of carriers combined with one or more inorganic elements, vitamins, or antimicrobial compounds. For example, a 20 standard diet may contain 79.5% corn; 17.4% soybean meal; 0.9% defluorinated phosphate; 0.65% limestone meal (35% Ca); 0.25% sodium chloride; 0.25% vitamin premix; 0.25% trace element premix; and 0.25% antimicrobial premix. Oats, sorghum and synthetic amino acids are sometimes added. In Europe, corn and 25 soybean meal are generally not as available nor as cost effective as beans, peas, barley, wheat, rape seed meal, cassava (tapioca), molasses, fish, bone, and meat meal. These are acceptable although not preferred amino acid sources.

In formulating the diets for gestating and lactating 30 swine, the Nutrient Requirements of Swine can be consulted to determine the amino acids, mineral elements, vitamins, and other dietary requirements for swine as a function of weight. The diet should contain between 5 and 30% by weight crude protein and be formulated for the specific use as a gestation

or a lactation diet. The following are recommended daily nutrient levels during gestation and lactation expressed in grams per head per day (g/hd/day) except where noted otherwise:

5

TABLE 1

| COMPONENT | GESTATION | LACTATION |
|------------------------------|------------------|------------------|
| Crude Protein | 250 | 899 |
| Lysine | 11 | 44 |
| Tryptophan | 2.5 | 11 |
| Threonine | 8 | 32 |
| Minerals | | |
| Calcium | 16 | 48 |
| Phosphorus | 14.5 | 43 |
| Salt | 9 | 27 |
| Copper, mg | 30 | 90 |
| Iodine, mg | .54 | 1.6 |
| Iron, mg | 300 | 900 |
| Manganese, mg | 72 | 216 |
| Selenium, mg | .18 ^a | .54 ^b |
| Zinc, mg | 300 | 900 |
| Vitamins | | |
| Vitamin A, IU | 20,000 | 60,000 |
| Vitamin D, IU | 3,000 | 9,000 |
| Vitamin E, IU | 80 | 240 |
| Vitamin K, mg | 8 | 24 |
| Riboflavin, mg | 15 | 45 |
| Niacin, mg | 90 | 270 |
| d-Pantothenic Acid, mg | 52 | 156 |
| Vitamin B ₁₂ , mg | .06 | .18 |
| Folic Acid, mg | 3 | 9 |
| Biotin, mg | .4 | 1.2 |
| Choline, mg | 1,000 | 3,000 |

40

^a legal addition if fed 4lb/hd/day

^b assumes at least 12lb/day feed intake of a diet containing .80% lysine

^c menadione sodium bisulfite (MSB) or equivalent

The feeds for gestating swine are different from the feeds for lactating swine. Generally, a requirement for protein, lysine, tryptophan and threonine is from about 3.5 to about 4 times higher for lactating swine. The components necessary for both types of feeds are generally in the following ranges expressed in pounds of a component per 2000 pounds of feed:

10

TABLE 2

| | COMPONENT | GESTATION FEED | LACTATION FEED |
|----|-----------------------------|----------------|----------------|
| 15 | Milo or Corn, lb | 1,533-1,684 | 1,359-1,568 |
| | Soybean Meal, lb (46.5%) | 235-379 | 343-557 |
| | Monocalcium Phosphate, lb | 37-46 | 41-45 |
| 20 | Limestone, lb | 20 | 19-20 |
| | Salt, lb | 10 | 10 |
| | Sow Add Pack, lb | 5 | 5 |
| 25 | Vitamin Premix, lb | 5 | 5 |
| | Trace Mineral Premix, lb | 3 | 3 |
| | Selenium Premix, lb | 1 | 1 |
| | Lysine, % | .55-.75 | .70-1.0 |
| | Ca, % | .80-.90 | .90 |
| | P, % | .70-.80 | .80 |

30

Suitable swine to be fed the diet of the present invention include but are not limited to all standard breeds of swine such as large white breeds and swine derived from specific breeding companies such as PIC, Newsham and Dekalb.

The feed schedule and feed rates used with the present method can be any standard schedule and rate used in the art. Generally, gestating swine are fed from about 4 to about 6 pounds of the diet per day, and preferably from about 4 to about 5 pounds per day. Lactating swine are generally fed from about 9 to about 15 pounds of the diet per day, and preferably from about 13 to about 14 pounds per day. Generally, the feed is administered from 1 to 2 times a day for gestating swine and from 1 to 2 times a day for lactating swine.

10 The following non-limiting example is representative of the present invention.

EXAMPLE: Effect of L-carnitine Fed During Lactation on Sow and Litter Performance and Milk Composition

15 A total of 27 first and second parity sows (PIC Line C-15) were used to determine the effect of feeding 50 ppm L-carnitine on the sow and litter performance. Sows were randomly assigned to either control or test dietary treatment on day 110 of gestation.

20 A corn-soybean meal based diet was formulated to contain 1.00% lysine, 0.9% Ca and 0.8% P. All other nutrients were in excess of NRC (1988) estimates, and included 68% corn; 27.58% soybean meal; 2.05 monocalcium phosphate; 1.13% limestone meal; 0.5% sodium chloride; 0.25% vitamin premix; 0.15% trace element premix; and 0.25% sow add mix (containing Mn, Fe, Zn, Cu, I and Se). Control diet contained 0.1% corn starch which was replaced by 50 ppm L-carnitine in the experimental diet. Sows were fed 4 lb of diet/day until farrowing. From farrowing until weaning (day 21), the sows were allowed *ad libitum* access to feed. Feed intake was measured weekly. Within 24 hours from farrowing, litters were equalized within dietary treatment. Pigs were weighed on day 0, 7, 14, and 21 to determine pig and litter weight gain. Sows were weighed on day 110, farrowing and weaning. Sows were ultrasonically

scanned for last rib fat debt at farrowing and weaning. Milk samples were collected from all sows on day 14 of lactation. Milk samples were analyzed for percentage of lipid, dry matter, protein ash and lactose.

5 The data were analyzed using the GLM procedure of SAS (1988). Because of the differences observed in initial number of pigs born, pig performance data was analyzed using days of lactation and number of pigs equalized as covariates. Sow performance data used days of lactation as a covariate.

10 The results of feeding sows an experimental diet containing 50 ppm L-carnitine are represented in Table 2.

TABLE 3

| Item | Control | Carnitine | CV | P value |
|----------------------------------|---------|-----------|-------|---------|
| No. of Litters | 14 | 13 | -- | -- |
| No. of Pigs Born | 11.01 | 13.45 | 22.49 | .06 |
| No. of Pigs Born Alive | 10.94 | 12.60 | 21.30 | .15 |
| No. of Pigs Equalized per Litter | 10.79 | 11.92 | 9.87 | .01 |
| Litter Birth Weight, lb | 38.46 | 37.77 | 14.41 | .78 |
| Pig Birth Weight, lb | 3.37 | 3.36 | 14.08 | .93 |
| Litter Weaning Weight, lb | 109.95 | 121.36 | 20.63 | .29 |
| Pig Weaning Weight, lb | 10.96 | 12.15 | 14.99 | .13 |
| Pig Survival, % | 89.96 | 86.57 | 9.98 | .39 |
| Sow ADFI, lb | 11.76 | 12.38 | 7.90 | .15 |
| Sow Weight Charge, lb | -3.202 | 4.25 | -400 | .86 |

| | | | | |
|----------------------------------|-------|-------|-------|-----|
| Sow Last Rib Fat Change | 0.523 | 0.14 | 571 | .42 |
| Milk Composi- tion, % | | | | |
| Lipid | 6.01 | 5.56 | 16.08 | .26 |
| Dry Matter | 16.61 | 16.32 | 4.96 | .41 |
| CP | 5.57 | 5.40 | 9.44 | .44 |
| Ash | .21 | .21 | 7.56 | .85 |
| Lactose | 4.81 | 5.15 | 13.21 | .24 |

The number of pigs born alive was higher in the sows fed the carnitine diet: after equalization, sows fed carnitine had approximately one pig more per litter. Litter and pig birth weight were not affected by dietary carnitine. However, pig weaning weight increased about 10% ($P<.13$) in litters from sow fed carnitine. This increase is likely to result from carnitine's influence on fatty acid metabolism.

Pig survival from farrowing to weaning and sow feed intake were not affected by carnitine. However, sows fed the control diet tended to loose weight in comparison to sows fed carnitine that tended to gain weight in the period from farrowing to weaning. This suggests that sows fed carnitine were more efficient at utilizing dietary fat.

Milk composition tested on day 14 of lactation was not significantly affected by added carnitine. This suggests that increased pig and litter weaning weight is a result of increased milk production and/or the level of carnitine in milk of sows fed carnitine rather than a change of milk composition.

In conclusion, these results suggest that carnitine in a gestating and lactating sow feed improves the litter and pig weaning weight as well as a number of pigs per litter.

Having described this invention and its benefits in detail above, it will be apparent that a skilled practitioner can make modifications and changes of the invention without departing from the scope or spirit of the claims which follow.

What is claimed is:

1 1. A feed formulation for gestating and lactating
2 swine comprising carnitine in an amount effective to increase
3 at least one of the following: number of pigs per litter,
4 litter weaning weight, and pig weaning weight.

1 2. The formulation of claim 1 wherein the carnitine
2 is L-carnitine or a salt thereof.

1 3. The formulation of claim 1 wherein the amount of
2 carnitine is from about 5 to about 5,000 ppm of the feed.

1 4. The formulation of claim 1 wherein the amount of
2 carnitine is from about 5 to about 200 ppm of the feed.

1 5. The formulation of claim 1 further comprising
2 from about 12% to about 30% by weight of crude protein.

1 6. A method for feeding gestating and lactating
2 swine comprising feeding a diet comprising carnitine in an
3 amount effective to increase at least one of the following:
4 number of pigs per litter, litter weaning weight, and pig
5 weaning weight.

1 7. The method of claim 6 wherein the carnitine is
2 L-carnitine or a salt thereof.

1 8. The method of claim 6 wherein the amount of
2 carnitine is from about 5 to about 5,000 ppm of the feed.

1 9. The method of claim 6 wherein the amount of
2 carnitine is from about 5 to about 200 ppm of the feed.

1 10. The method of claim 6 wherein the diet further
2 comprises from about 12% to about 30% by weight of crude
3 protein.

1 11. A method for increasing pork productivity
2 comprising the steps of:
3 (a) supplementing a swine diet with an effective
4 amount of carnitine, and
5 (b) feeding the supplemented diet to swine during
6 the period of gestation, lactation or both.

1 12. The method of claim 11 wherein the pork
2 productivity is increased by increasing at least one of the
3 following: number of pigs per litter, litter weaning weight,
4 and pig weaning weight.

1 13. The method of claim 11 wherein the carnitine is
2 L-carnitine or a salt thereof.

1 14. The method of claim 11 wherein the effective
2 amount of carnitine is from about 5 to about 5,000 ppm of the
3 feed.

1 15. The method of claim 11 wherein the effective
2 amount of carnitine is from about 50 to about 200 ppm of the
3 feed.

1 16. The method of claim 11 wherein the gestating and
2 lactating swine diet comprises from about 12% to about 30% by
3 weight of crude protein.

ABSTRACT

The present invention relates to a method of feeding gestating and lactating swine and a feed formulation which
5 enhances pork productivity by increasing litter and pig weaning weights and the number of pigs per litter. Swine diets of this invention include carnitine, such as L-carnitine or L-carnitine salts. Carnitine is added to the swine diet in an amount effective to increase the number of pigs per litter and the
10 litter and pig weaning weights.

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on April 22, 1997 (Date of Deposit)

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Date
J. Karan
Name



File No.: 5407/0B426

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JIM L. NELSEN, ET AL.

Serial No.: 08/759,765 Group Art Unit:

Filed: December 3, 1996 Examiner:

For: CARNITINE SUPPLEMENTED DIETS
FOR GESTATING AND LACTATING SWINEPETITION FOR EXTENSION OF TIME

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Washington, DC 20231

Sir:

This is a petition to extend the time for filing a response to the Notice to File Missing Parts of Application dated February 7, 1997 in the above-identified patent application.

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| [x] | first month, fee \$110 | \$ <u>110.00</u> |
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| [] | third month, fee \$540 (\$930) | \$ <u>--</u> |
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SUBTOTAL = \$110.00

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Respectfully submitted,

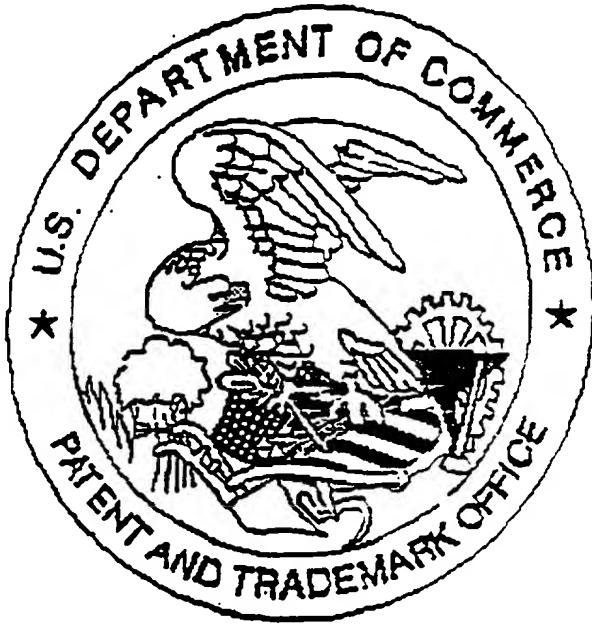


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Dated: April 22, 1997

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